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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/475,721   | 12/30/1999  | MATTHEW S. REIMINK   | 1610.IUS01          | 6766             |
| 27367  | 7590        | 04/27/2006           | EXAMINER            |                  |
| WESTMAN CHAMPLIN & KELLY, P.A.<br>SUITE 1400 - INTERNATIONAL CENTRE<br>900 SECOND AVENUE SOUTH<br>MINNEAPOLIS, MN 55402-3319 |             |                      |                     | HON, SOW FUN     |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1772   |             |                      |                     |                  |

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/475,721             | REIMINK ET AL.      |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Sow-Fun Hon            | 1772                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 April 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5-20,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,5-20,31 and 32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION**

***Response to Amendment***

1. A prior art rejection of claims 12-14 was inadvertently omitted from the last Office action and, therefore, the finality of that action is withdrawn. Furthermore, the amendment to claims 1-3, 5-9, 31-32 has been entered, and new grounds of rejection are set forth below.

***Rejections Withdrawn***

2. The 35 U.S.C. 112, 2<sup>nd</sup> paragraph rejection of claim 20 is withdrawn due to Applicant's amendment dated 04/07/06.

3. The 35 U.S.C. 103(a) rejections of claims 1-3, 5-9, 31-32 are withdrawn due to Applicant's amendment dated 04/07/06.

4. The 35 U.S.C. 103(a) rejections of claims 10-11, 15-20 over the primary combination of Lenkei in view of Reul and Koppert are withdrawn due to the new interpretation of the prior art references in the new rejections set forth below.

***New Rejections***

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-3, 8-11, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Reul (US 4,263,680).

Regarding claim 1, Reul teaches a medical device (prosthetic heart valve, column 6, line 29) comprising a composite (valve member 1, column 5, line 41, Fig. 3) having an inorganic substrate (metal substrate 12, column 5, lines 45-47, Fig. 3) and a polymer applied on all of the substrate surfaces (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3), the polymer forming a structure shaped differently from the structure of the substrate, and providing the form of the device (Fig. 3, hinge flap is formed in one piece with the valve member and consists of the same blood-compatible synthetic material with which the valve member is coated, integrally cast in the course of the coating process, column 4, lines 39-45, valve ring is coated with the same blood-compatible synthetic material as the valve member, column 4, lines 47-49).

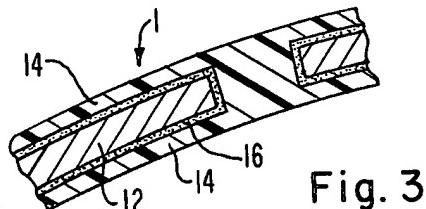


Fig. 3

Regarding claim 2, Reul teaches that the substrate comprises metal (column 5, lines 45-47).

Regarding claim 3, Reul teaches that the substrate comprises a ceramic (column 4, lines 18-24, ceramic used instead of metal).

Regarding claim 8, Reul teaches that the medical device comprises a heart valve prosthesis (prosthetic heart valve, column 6, line 29), the heart valve prosthesis

comprising a component (valve member 1, column 5, line 41, Fig. 3) that comprises the composite having the inorganic substrate metal substrate 12, column 5, lines 45-47, Fig. 3) and the polymer material (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3).

Regarding claim 9, Reul teaches that the polymer material has structure forming a slot (valve ring is provided with a slot, column 5, lines 30-32, valve ring is coated with the same blood-compatible synthetic material as the valve member, column 4, lines 47-49).

Regarding claim 10, Reul teaches a medical device prosthetic heart valve, column 6, line 29) comprising a composite component comprising an inorganic substrate (metal substrate 12, column 5, lines 45-47, Fig. 3) and a polymer member covering the substrate (blood compatible synthetic material 14, column 5, lines 41-44, Fig. 3), wherein the composite component can be bent through a cross section of the composite component (thin valve member including metal substrate can be bent, 03-0.4 mm, column 3, lines 40-45), and wherein the polymer member contacts bodily fluids and separates the bodily fluids from the substrate (blood-compatible synthetic material, column 4, lines 40-45). The composite component is flexible by virtue of its thickness (less than 0.3 – 0.4 mm, column 3, lines 40-42), and its composition (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45).

Regarding claim 11, Reul teaches that the heart valve member is preferably less than 300 microns (0.3 mm, column 3, lines 40-50), meaning that the metal substrate is a metal foil which has a thickness of less than 300 microns, which is within the claimed thickness range of less than about 500 microns.

Regarding claims 16-17, the flexible composite component of Reul is expected to have the ability to be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit, by virtue of its composition (metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45).

Regarding claims 18-19, Reul teaches that the number of stress cycles completed up to March 3, 1978 was 98 million with no appearance of fatigue (column 6, lines 14-23). Thus the flexible composite component of Reul is expected to have the ability to be bent about 60 degrees for about 40 million cycles without significant structural failure. Reul teaches that the life span aimed at is 367 million stress cycles at normal frequency (column 6, lines 20-23), which is within the range of about 400 million cycles without significant structural failure.

***Claim Rejections - 35 USC § 103***

6. Claims 5-7, 12-14, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reul as applied to claims 1-3, 8-11, 16-19 above, and further in view of Pietsch (US 4,778,461).

Reul teaches the heart valve prosthesis comprising the composite having an inorganic substrate and a polymer applied on all of the substrate surfaces, covering the substrate, as described above.

Regarding claims 5, 32, Reul fails to teach that the polymer is polyethersulfone or polycarbonate.

However, Pietsch teaches a heart valve prosthesis (abstract), wherein the polymer is polyethersulfone or polycarbonate, for the purpose of providing a physiologically acceptable material (column 3, lines 45-55). Polycarbonate is a rigid polymer by virtue of its composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyethersulfone, or polycarbonate which is a rigid polymer, as the polymer of Reul, in order to provide a physiologically acceptable material for the heart valve prosthesis, as taught by Pietsch.

Regarding claims 12, 31, Reul fails to teach that the polymer is polyurethane or polydimethylsiloxane, or that it is crosslinked.

However, Pietsch teaches a heart valve prosthesis (abstract) wherein the polymer is polyurethane for providing blood compatibility (column 4, lines 34-40) as well as polydimethylsiloxane (column 5, lines 5-10, silicone rubber, column 4, lines 54-65),

which is crosslinked for the purpose of providing flexibility coupled with high breaking strength (column 4, lines 21-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polyurethane or polydimethylsiloxane, as the polymer of Reul, in order to provide blood compatibility, and to have cross-linked it, in order to provide flexibility coupled with high breaking strength, to the heart valve prosthesis, as taught by Pietsch.

Regarding claims 6-7, 13-14, Reul fails to teach the thickness of the polymer member.

However, Pietsch teaches that the wall thickness of the polymer can be 50 to 1000 microns (column 2, lines 50-55), which is within the claimed range of at least about 10 microns, overlaps the claimed range of from about 100 microns to about 2000 microns, and of from about 10 microns to about 500 microns, and encompasses the claimed range of from about 50 microns to about 300 microns, for the purpose of providing the desired Shore hardness and breaking strength of the flexible material (column 2, lines 50-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the polymer member of Reul with a thickness within the claimed ranges, in order to provide the desired Shore hardness and breaking strength for the flexible polymer member, as taught by Pietsch.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reul as applied to claims 1-3, 8-11, 16-19 above, and further in view of Lenkei (US 4,597,767).

Reul teaches that the medical device comprises a heart valve prosthesis (prosthetic heart valve, column 6, line 29) comprising a composite component comprising an inorganic substrate and a polymer member covering the substrate, as described above, but fails to teach that the composite component comprises leaflets.

However, Lenkei teaches a medical device which comprises a heart valve prosthesis (column 4, lines 39-45) comprising a flexible composite component comprising leaflets, wherein each leaflet comprises an inorganic substrate which comprises a metal foil (stainless steel, column 4, lines 19-25). The flexible component can be bent through a cross section of the flexible component (stainless steel foil).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the heart valve composite component of Reul with leaflets, in order to provide the desired heart valve prosthesis, as taught by Lenkei.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reul, as applied to claims 1-3, 8-11, 16-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Reul teaches the heart valve prosthesis comprising polymer member as described above, and fails to teach that the composite further comprises a diamond-like carbon coating over at least a portion of the polymer member.

However, Sumimoto teaches a diamond-like carbon coating over the polymer member for the purpose of providing good antithrombosis and durability properties to the heart valve prosthesis (artificial heart valve, abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a diamond-like carbon coating over at least a portion of the polymer member of the heart valve prosthesis of Reul, in order to obtain good antithrombosis and durability properties, as taught by Sumimoto.

#### ***Response to Arguments***

9. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

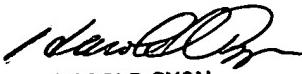
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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon.

Sow-Fun Hon

04/20/06

  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
1772

4/24/06